

National Institute of Allergy and Infectious Diseases

2019 Annual Network Meeting

Sterile Product Preparation: Equipment, Technique, Monitoring & Training



NIAID



National Institute of
Allergy and
Infectious Diseases

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Disclaimer

- This presentation is meant **for informational purposes only!**
 - It is not all encompassing or all inclusive of subject matter presented
 - This is NOT considered training for sterile product preparation or certification for aseptic technique
 - Presentation contains a broad overview of best practices associated with sterile product preparation and not all information contained within will apply to all sites
 - All sites must comply with all protocol-specific documents and all applicable local, institutional, state and in-country requirements, and this presentation does not supersede these requirements



Agenda

- Goal of Sterile Product Preparation
- Facilities & Equipment
- Washing and Garbing
- Cleaning and Disinfecting
- Aseptic Technique
- Environmental Monitoring
- Personnel Training and Evaluation



Goal of Sterile Product Preparation



Sterile Product Preparation: Ultimate Goal!

- Utilizing good practices along with correct equipment to prevent harm (***including death***) to patients that could result from:
 - Microbial contamination (non-sterility)
 - Excessive bacterial endotoxins
 - Variability in the intended strength of correct ingredients
 - Unintended chemical and physical contaminants
 - Ingredients of inappropriate quality in preparing sterile products

Is it Really that Important?

New England Compounding Center (NECC); 2012

- Almost 800 people developed fungal meningitis from methylprednisolone epidural injections
 - 76 patients who received injections died
 - FDA sterility testing found viable microbial growth in 50/50 vials tested
- Upon inspection, FDA also observed the following:
 - Mold and bacteria in the Clean Room
 - Yellow and green residue on workspaces
 - Tarnished discoloration on trays that held sterilized equipment (spatulas, beakers, etc.)
- **Consequences:**
 - Multiple people, including pharmacists, convicted of federal criminal charges with imprisonment
 - Former supervisory pharmacist sentenced to 8 years in prison; convicted of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead
 - Multiple fines were imposed

[CNN news segment on findings at NECC](#)

[FDA Inspection Report](#)

Is this still an issue?

Yes! Problems keep occurring!

Guardian Pharmacy, November 2017

- At least 43 patients reported experiencing vision impairment and loss after being administered triamcinolone-moxifloxacin intravitreal injections
 - FDA collected and tested samples of the injections and inspected the pharmacy
- FDA inspected facility and noted that “***drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health***”
- FDA findings included:
 - Inadequate system for cleaning and disinfecting
 - Failure to establish and follow written procedures to prevent contamination including failure to validate all aseptic and sterilization procedures
 - Failure to establish adequate system for monitoring environmental conditions in aseptic processing areas
- **Consequences:** Pharmacy ordered to stop preparing sterile drugs until it could comply with regulations
 - Company also had to pay the costs of the FDA's future efforts to ensure pharmacy compliance

[FDA Inspection Report](#)

And Occurring...

Ranier's Compounding, May 2018

- Observations from FDA Inspection led to an injunction against the company where it was forbidden to make sterile products until it could meet standards
- FDA findings included
 - Personnel touched equipment/surface outside of the ISO 5 classified area and then continued preparation without changing or sanitizing gloves
 - Technician's hair was not fully covered while working in the ISO 5 classified area
 - Equipment/materials/supplies not disinfected before entering aseptic areas
 - Disinfecting agents/wipes used in aseptic areas were not sterile
 - Floor of clean room had visible dirt, stains, or residue; dust on overhangs
- **Consequences:** Besides the injunction, company issued recall for sterile products prepared between 17-Jan-18 and 10-Jul-18
- [FDA Inspection Report](#)

Problem Occurred within the Past Year!

Greenpark Compounding Pharmacy October, 2018

- FDA inspection reveals unsanitary practices and pharmacy was issued a warning
 - *“The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk”*
 - Personnel with exposed skin and non-sterile garb within ISO Class 5 area
 - Re-sanitizing gloves with non-sterile agent
 - Using wipes for disinfecting that were not sterile
 - ***“FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations”***

[FDA Inspection Report](#)

Examples of Common Problems found during FDA Inspections

Environmental

- Vermin
- Mold & bacterial growth
- Rust
- Hairs
- Paint chips
- Standing water

Equipment

- Unclean and/or unsterilized tools/equipment
- Improper ventilation

Technique

- Improper handling that led to cross contamination
- Failure to wear the right personal protective equipment (PPE)

Why Should I Care???

- May increase morbidity and mortality that includes hospitalization and death
- Poor patient outcomes
- Violations/findings could lead to:
 - Pause in enrollment of study participants
 - Participants not being able to receive study product from the site
 - Transfer of study participants to another site
 - Potential for compromised data integrity or protocol deviations

**MUST BE PROACTIVE
TO ENSURE
PARTICIPANT SAFETY!!!**

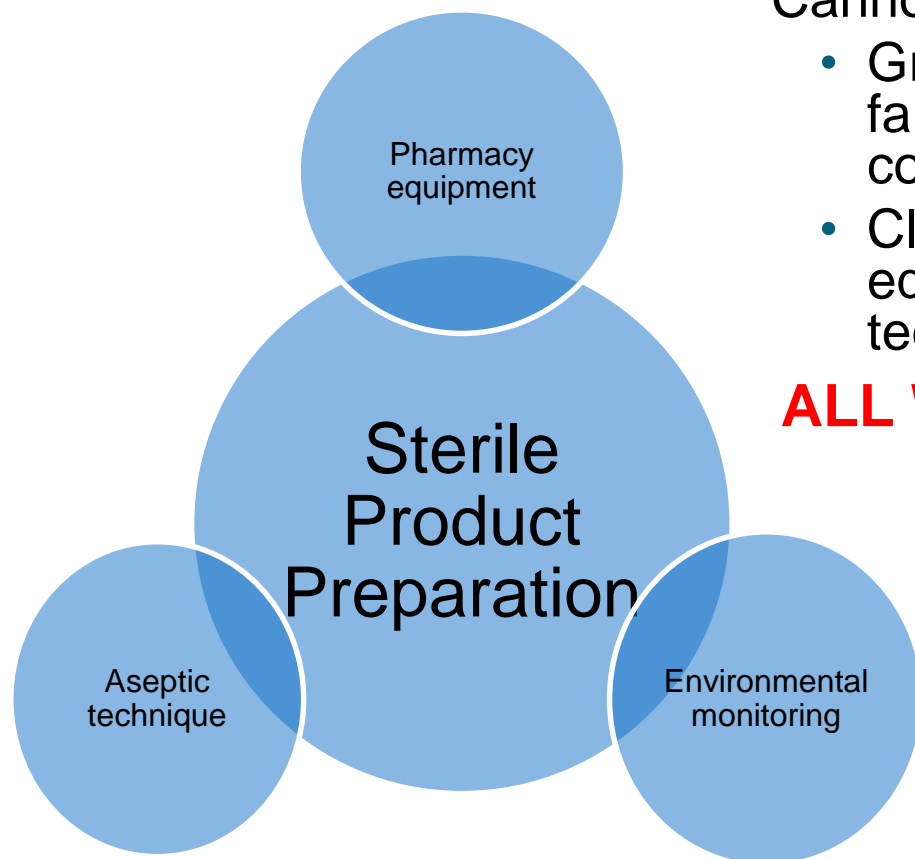


What is Involved?

Cannot have:

- Great aseptic technique and faulty equipment in a compromised environment
- Clean functioning equipment and poor aseptic technique

ALL WORK TOGETHER!!!



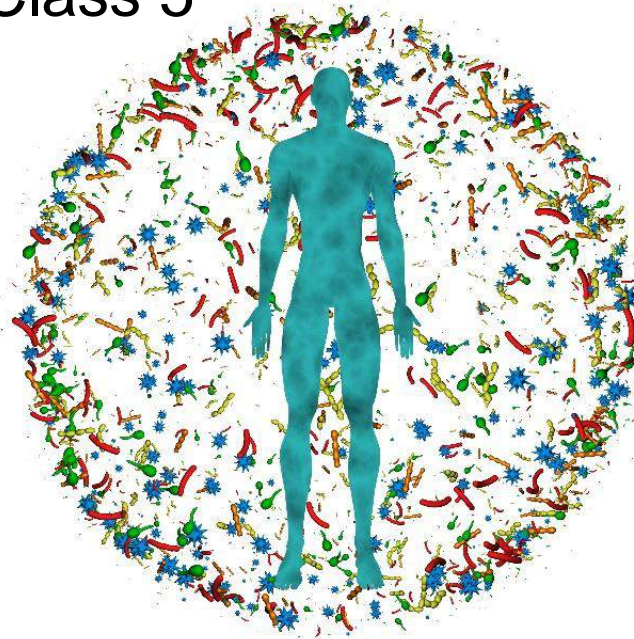
Facilities & Equipment



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Facility Design: Air Quality

- Proper air quality is essential
- Usually controlled by a device or a room
- Measured by **ISO** (International Organization for Standardization) Class
 - Sterile preparation is usually required to be done in an environment that is ISO Class 5



Facility Design:

Ante Room vs. Clean Room (Layout)

■ Ante Room:

- Room between the Clean Room and common area
- Area where staff wash and garb before entering a Clean Room

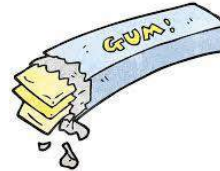
■ Clean Room (Buffer Area):

- Room where Laminar Workbench/BSC/Isolator is placed
- Any equipment brought into the Clean Room must be cleaned and disinfected beforehand

Consult with your facility engineer, or equivalently trained personnel, for appropriate facility design necessary to comply with standards

Examples of Items that are *PROHIBITED* in Ante Room/Clean Room:

- Food/Gum
- Drink
- Smoking
- Jewelry
- Artificial nails or extenders
- Fingernail polish
- Cell Phones



Equipment:

Laminar Workbench/BSC/Isolator - HEPA Filter

- Each contain high-efficiency particulate air (HEPA) filter
 - Removes more than 99.97% of particles as small as 0.3 microns
 - Used to keep rooms or devices at ISO Class 5

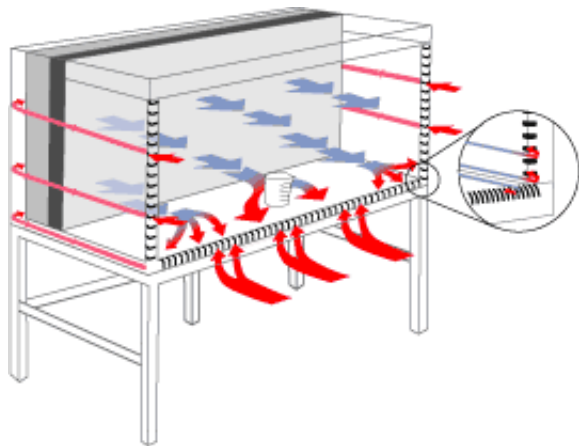


Equipment: Laminar Airflow Workbench

Type	Airflow Pattern	Product Protection	Personnel Protection	Environmental Protection
Horizontal LFH ("Clean Bench")	HEPA filtered, Horizontal	Yes (Never to be used for cell culture materials, infectious or hazardous drug formulations)	No	No
Vertical LFH ("Clean Bench")	HEPA filtered, Vertical	Yes (Never to be used for potentially infectious or toxic materials or antineoplastics)	No	No

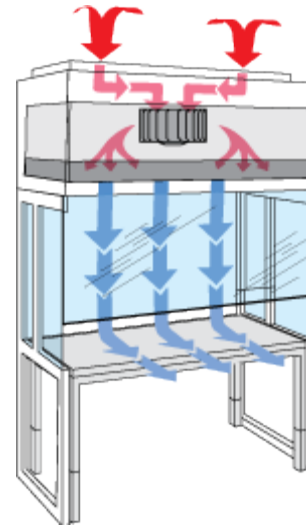
References: http://www.cdc.gov/biosafety/publications/bmbl5/BMML5_appendixa.pdf; <https://www.bakerco.com/introduction-biological-safety-cabinets>

Equipment: Laminar Airflow Workbench



Horizontal LFH

Versus



Vertical LFH

Equipment:

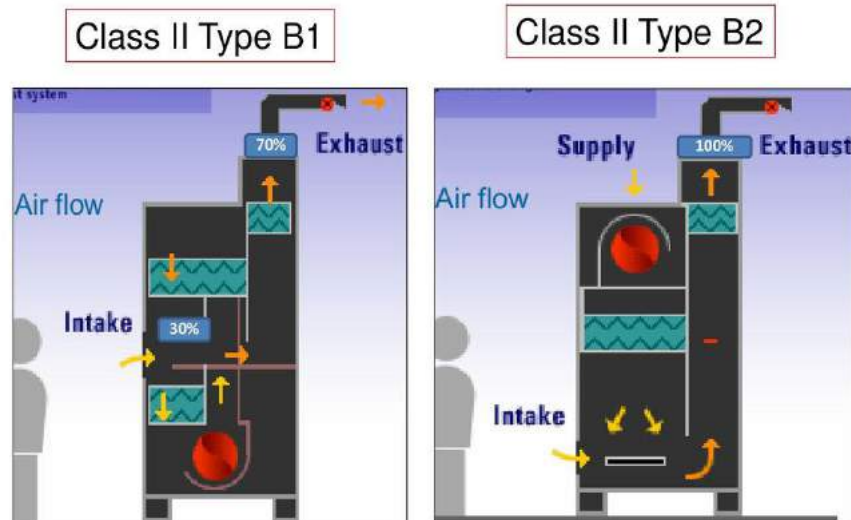
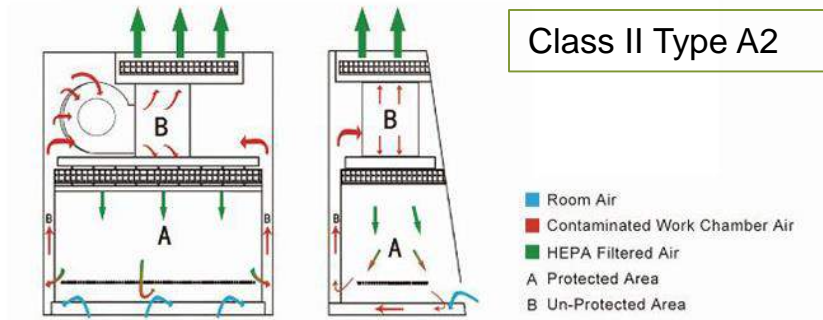
Classification of BSCs/Isolators

Type	Airflow Pattern	Product Protection	Personnel Protection	Environmental Protection
Class I	In at front, rear and top through HEPA filter	No	Yes	Yes
Class II Type A1 (Considered Obsolete)	70% recirculated through HEPA filter; 30% exhaust through HEPA filter	Yes	Yes	Yes
Class II Type A2	Same as Class II, Type A, but plenum is under negative pressure to room and exhaust air is ducted	Yes	Yes	Yes
Class II Type B1	30% recirculated through HEPA filter; 70% exhaust via through HEPA filter and hard ducted	Yes	Yes	Yes
Class II Type B2	No recirculation through HEPA filter and hard ducted	Yes	Yes	Yes
Class III (Isolator)	Supply air inlets and exhaust through 2 HEPA filters and exhausted to outside via hard connection	Yes	Yes	Yes

References: http://www.cdc.gov/biosafety/publications/bmbl5/BMML5_appendix.pdf;
<https://www.bakerco.com/introduction-biological-safety-cabinets>

Equipment:

Different Airflow of Type II BSCs



Equipment: Compounding Aseptic Isolator

- Closed system: direct work surface does not have contact with air in room
- Two Types:
 - Compounding Aseptic
 - Can be used for non-hazardous drugs
 - Has a positive (+) air pressure
 - Compounding Aseptic *Containment*
 - Can be used for hazardous drugs
 - Has a negative (-) air pressure



Equipment: Operation Pearls

- The BSC/Workbench/Isolator **MUST** be turned on for the unidirectional airflow through the filter to work
 - Airflow should not be turned off throughout the work day
- It **MUST** be running for a certain duration of time before sterile products may be prepared
 - Specified time may be different for each type & per distinct manufacturer
 - General guidance: equipment must be running for at least 30 minutes before use
 - ***Refer to the manufacturer's recommendations for your specific equipment !!!***

Washing and Garbing



Washing and Garbing

- Must follow all institutional and in-country regulations
- Before preparation of sterile product:
 - Remove outerwear such as a coat, hat, etc.
 - Remove all visible jewelry (hand, wrist, etc.)
- Put on Personal Protective Equipment (PPE) as required
 - Shoe covers, head covers, facial masks, gowns, etc.



Washing and Garbing: Proper Order

Step 1: Put on shoe covers

Step 2: Put on hair cover

- head & facial

Step 3: Put on face mask

Step 4: Wash hands and forearms vigorously with antibacterial soap and warm running water for at least 30 seconds

- Clean all the way up to the elbows
- Scrub under the fingernails

Washing and Garbing: Proper Order (Cont.)

Step 5: Completely dry hands and arms with non-shedding disposable towel

- If non-automatic dispenser, make sure towel is ready for use before washing hands and arms



Step 6: Put on a disposable gown with cuffs and a closure at the neck



Step 7: Clean hands again with a waterless, alcohol-based surgical scrub



Step 8: Put on sterile, powder-free gloves

- Should overlap cuffs on gown



Step 9: Apply 70% sterile, isopropyl alcohol to gloves and allow to dry

Washing and Garbing: Can Gowns be Re-used?

- Can you re-use gowns?
 - For *non-hazardous* drug preparations, gowns may be re-used within the same shift
 - All other PPE **cannot** be re-used
 - For *hazardous* drug preparations, gowns should be removed and discarded before leaving preparation area and/or immediately if contaminated

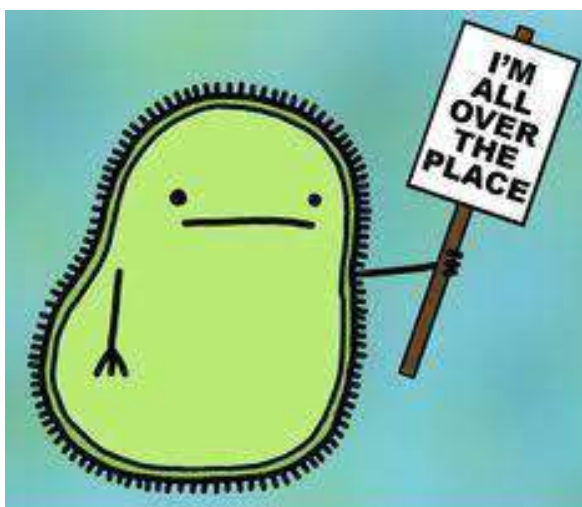
REMINDER: before resuming sterile product preparation, all procedures listed for washing and garbing must be repeated!

Cleaning and Disinfecting



Cleaning and Disinfecting

- Routine cleaning and disinfecting are required for maintaining a safe environment
 - Even if using good aseptic technique, contaminated surfaces will contaminate the sterility of prepared products



NotAise Det.com

Cleaning and Disinfecting

Cleaning (first step)

- Removes visible soil from surfaces
- Use a germicidal detergent and water
- Scrubbing will remove large number of microorganisms and improve the subsequent disinfecting process

Disinfecting (Second step)

- Kills viable* microorganisms such as bacteria, fungi, and viruses that may be present after cleaning
- Examples of common disinfectants used in health care:
 - Isopropyl alcohol 60-95%
 - Accelerated hydrogen peroxide 0.5
 - Bleach (e.g., sodium hypochlorite) 2% v/v solution

Some products may be considered multipurpose agents that both clean and disinfect

*Viable: capable of living, developing, or germinating under favorable conditions
(<https://medical-dictionary.thefreedictionary.com/viable>)

Cleaning and Disinfecting: BSC/Isolator

- Use a clean, lint-free, non-shedding wipe
- Clean from top to bottom and from back to front
 - Move contaminants away from the HEPA filter
 - Clean from upstream (closest to filter) to downstream of airflow
 - For BSCs
 - Start with top of rear wall, move down wiping in a horizontal motion
 - Continue with fixtures, the sides, and lastly the work surface
- Nothing should ever touch the HEPA filter
 - Avoid spraying disinfectant in the direction of the filter
 - Coughing or talking should be directed away from the filter

Cleaning and Disinfecting: How Often?

- Guidance on recommended minimum frequency of cleaning and disinfecting activities

Area	Frequency
Biosafety Cabinet, Laminar Airflow Workbench, Compounding Aseptic Isolator	<ul style="list-style-type: none">• Beginning of each shift• Before product preparation• Every 30 minutes while preparing products• After Spills• When surface contamination is known or suspected
Counters and Work Surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage Shelving	Monthly

Cleaning and Disinfecting: SOP

- Each site should develop, follow and maintain an SOP that outlines cleaning & disinfecting procedures for Clean Room, Ante Room, workbench/BSC/isolator
 - SOP should align with institutional practices and equipment (i.e.; BSC/Isolator) manufacturer's recommendations
 - Should take into account who will be trained to perform cleaning & disinfecting activities and how often
 - Should include how cleaning & disinfecting activities will be documented

Aseptic Technique



Aseptic Technique

- **“Any health care procedure in which added precautions, such as use of sterile gloves and instruments, are used to prevent contamination of a person, object, or area by microorganisms”**

Mosby's Medical Dictionary, 9th edition. © 2009, Elsevier.



Aseptic Technique: Workspace Considerations

- Once sterile preparation has begun, **REMAIN** in the Workbench/BSC/Isolator
 - Gather all necessary items (product, needles, syringes, sterile alcohol pads, etc.) that will be needed before starting
 - Remember! Always place items on the side so as not to block the filter and/or the area where the sterile product will be prepared
- **ALWAYS** make sure you are preparing the product **AT LEAST 6 inches** inside either a workbench or BSC
 - Minimize contact with possibly contaminated room air

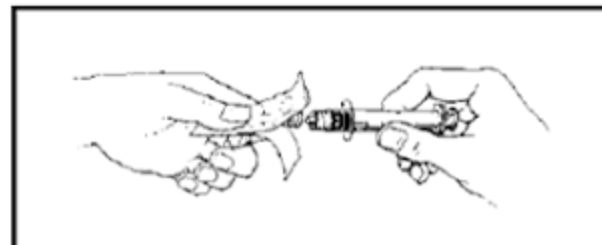
Aseptic Technique: Workspace Considerations

- It is CRITICAL that while working in a workbench/BSC/Isolator, nothing should interrupt the airflow between the HEPA filter and the sterile product being prepared
 - Example: working in a Biological Safety Cabinet
 - Airflow is vertical (from top of BSC towards the bottom)
 - Make sure the product is in direct flow of air from the filter
 - Do not want hands or other objects in between the filter and the product being prepared
 - Work at least 6 inches inside of the BSC
 - Minimize movements as to not disrupt the air curtain



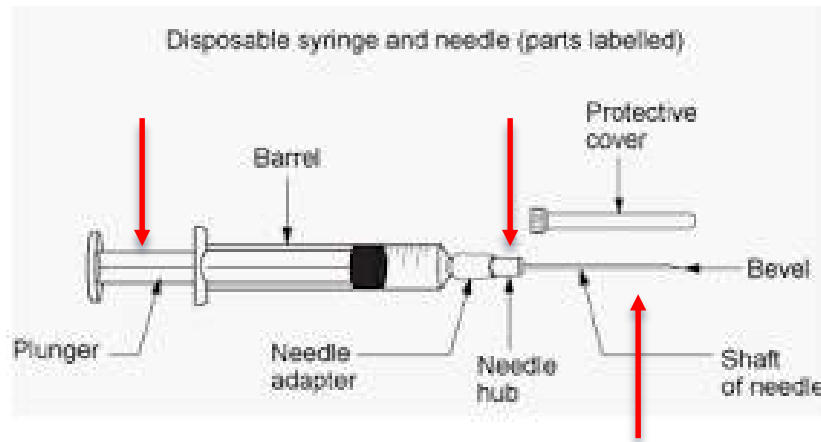
Aseptic Technique: Syringe & Needle Considerations

- Only use syringes and needles that come in sterile packaging
 - To maintain sterility, only open supplies within the running workbench/BSC/isolator
 - When attaching a needle to a syringe, peel the needle blister pouch half way open & grasp needle using peel pouch
 - Make sure to connect needle to syringe within airflow of the HEPA filter



Aseptic Technique: Syringe & Needle Considerations

- AVOID touching the portion of the plunger that goes into the syringe
 - This is a sterile area
 - Only touch the flat end at the top of the plunger when manipulating measurements



Red arrow indicate areas that should not be touched to maintain sterility

Aseptic Technique: Working with Vials or Glass Ampules

- Vials/Ampules are frequently exposed to outside contamination (shipping, pharmacy common areas, etc.)
- A cap or cover on the vial DOES NOT confirm sterility
- Vials/Ampules should be disinfected with 70% isopropyl alcohol before placement in workbench/BSC/isolator
- Only remove vial cap, or break open ampule, within a running workbench/BSC/isolator immediately prior to use

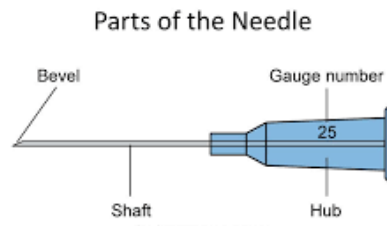
Aseptic Technique: Working with Vials

- Opening vials
 - Once cap/cover is removed, wipe the rubber stopper with sterile alcohol pad firmly in **ONE DIRECTION**
 - Removes particles from vial in addition to disinfecting
 - If stopper is wiped in a back and forth direction, there is a risk of just pushing particles around the top of the vial and not necessarily removing them



Aseptic Technique: Working with Vials

- Removing volume from vial
 - Insert needle into vial at an angle with the bevel (hole) of the needle facing up (away from stopper)
 - Pierce the rubber stopper with bevel tip facing upwards while simultaneously bringing syringe to an upright position
 - This technique will help to prevent rubber fragments from entering the vial and therefore aid in maintaining sterility
 - Remember! It is usually necessary to first add air into the vial that is equal to the volume to be withdrawn
 - This will avoid a vacuum within the vial



Aseptic Technique: Working with Glass Ampules

- Opening glass ampules
 - Make sure all fluid is on the bottom of the ampule before opening
 - Swirl the ampule upright or tap head of ampule with finger
 - Within the airflow of the HEPA filter, again wipe down ampule with alcohol pad and leave pad around the neck of the ampule. Snap the neck of the ampule to open.
 - Usually an indicator on the ampule on where to snap neck
 - DO NOT open in the direction of the HEPA filter



Aseptic Technique: Working with Filter Needles

- To be used when removing volume from a glass ampule, or when required
 - Example: for glass ampules, will prevent any glass particles from being drawn up into the syringe
- Once volume is withdrawn from ampule, **Remove** the filter needle **and replace** with new needle to then continue with preparation/dispensation
 - The same needle **CANNOT** be used for both withdrawing and injecting
 - This would cancel out the filter effect!



Aseptic Technique: Working with IV Bags/Other Containers

- Wipe down port of entry with alcohol swab within the airflow of the HEPA filter before use
 - Wipe port in one direction as previously discussed with vials (Do not wipe in a back and forth motion)
- Inspect finished product against a light or dark colored background
 - Looking for particulate matter or unexpected cloudiness



Aseptic Technique: General Reminders

- Limit number of supplies brought into preparation area
- Perform all calculations prior to preparing product
- Check expiration dates & outer integrity of all medications & supplies
- Work at least 6 inches (15.2 cm) inside work space
- When working in a laminar workbench, work no closer than 3 inches (7.6 cm) from very back of workbench
 - Do not want to be too close to HEPA filter where splashes or other events may compromise the filter
- ***Nothing should touch HEPA filter***

Aseptic Technique: General Reminders

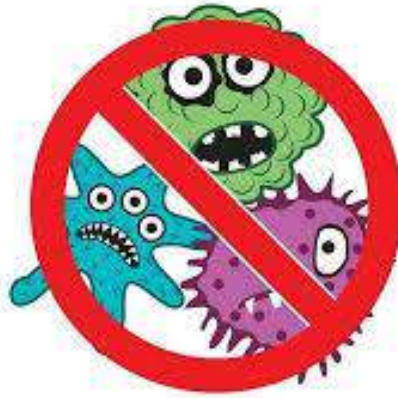
- Avoid Distractions
 - Possible cause of incorrect measurements
 - Possible cause of completing preparation steps in incorrect chronological order
 - Possible cause of incorrect aseptic technique
 - Example: conversations may cause the body to unintentionally turn and accidentally pulling product too far out of workspace
- Change sterile gloves periodically and/or immediately if contaminated; especially when extended time is needed working in workbench/BSC/isolator
 - e.g., multiple products being prepared, shift work, etc.

Aseptic Technique: General Reminders

- Label all products as appropriate with correct use by dates/times
- Do not discard materials used during sterile product preparation until final check/second verification has been performed and documented



Environmental Monitoring



Environmental Monitoring:

- Consists of **non viable** and **viable** particle testing
- Ensures equipment and processes are maintaining correct environment for sterile preparation of products

Non Viable vs. **Viable** particles

- **Non viable particles:** non-living particles that may act as transporting agents for viable particles
 - Examples: dust, mist, fumes
- **Viable particles:** organisms capable of living, developing, or germinating under favorable conditions, which may affect sterility
 - Examples: fungi, bacteria, virus, and spores



Environmental Monitoring:

- Sampling and testing should occur at a minimum:
 - At certification/recertification of new facility/equipment
 - After servicing or relocation/alteration of facility/equipment
 - If problems are identified with products, preparations, or employee technique
 - At least every 6 months or more frequently per institutional policies & procedures
- Results provide a snapshot in time. Need to look not only at current results, but also at trends

Environmental Monitoring: Non-Viable Particle Testing

- Intended to directly measure the performance of the Workbench/BSC/Isolator, Anteroom, and Clean room
- Tests for:
 - Total particle counts
 - Pressure differential
- Performed by qualified personnel
- Testing schedule as per manufacturer's specifications



Environmental Monitoring: Viable Airborne Particle Testing

- Consists of both air and surface sampling
- Tests for microbial contamination which could result from improper hand hygiene, garbing practices, aseptic technique, cleaning & disinfecting
- Should be performed and documented at least every 6 months or more frequently per institutional policies and procedures
- Usually can have the same company that is performing non-viable airborne sampling also perform viable airborne sampling

Personnel Training & Evaluation



Personnel Training and Evaluation

- How does your institution train new employees on preparing sterile products?
- How is the training assessed and documented?
- How often does re-training/re-assessment occur?



Personnel Training and Evaluation

- Training and competency assessment should be done upon hiring and before working independently. Re-training and re-assessment should occur at least every 12 months.
 - MAKE SURE TRAINING IS DOCUMENTED
- Training and evaluation should include demonstrated knowledge of:
 - Aseptic technique
 - Cleaning and disinfecting
 - Environmental monitoring requirements and processes
 - Washing and Garbing
 - Institutional policies involving sterile environment and QA procedures
 - SOPs, Work Instructions, Job Aids, etc.
- Evaluations should include Media Fill Tests and Gloved Fingertip Sampling

Personnel Training and Evaluation

Media Fill Tests

Media Fill tests

- Simulation tests that mimic everyday sterility procedures
- Objective way to assess if staff is performing proper aseptic technique along with proper washing, garbing, and other procedures
- A microbiological growth medium is substituted for drug product and final product is checked for cloudy or opaque appearance



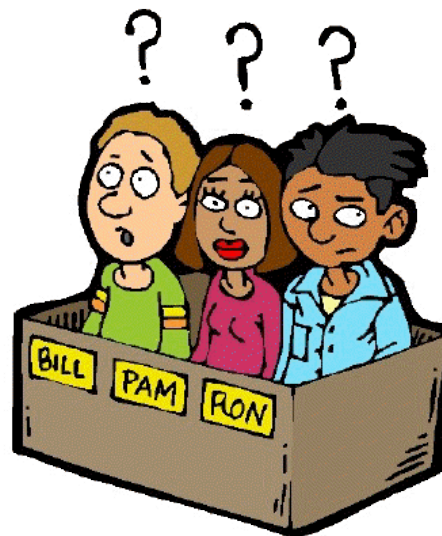
Personnel Training and Evaluation: Gloved Fingertip Sampling

Gloved Fingertip Sampling

- Assess garbing and disinfecting procedures
- Place a gloved fingertip(s) on sterile agar plate or similar device after hand washing and garbing
- All new personnel should successfully complete 3 samplings before being able to prepare sterile products independently



POP QUIZ!!!



Pop Quiz!

Question 1: Which of the following may be brought into the ISO Class 5 sterile preparation area?

- A: Food/Gum
- B: Cell Phones
- C: Jewelry
- D: Drink
- E: None of the Above

Answer: E

Pop Quiz!

Question 2: Which of the following does NOT protect product, personnel, and environment during product preparation?

- A: Laminar Flow Workbench
- B: Class IIA Biosafety Cabinet
- C: Class IIB Biosafety Cabinet
- D: Compounding Aseptic Isolator
- E: None of the above

Answer: A

Pop Quiz!

Question 3: Proper aseptic technique includes all of the following EXCEPT:

- A: Removing sterile packaging of needle and syringe only when inside the airflow of the HEPA filter
- B: Inserting needle into a vial at an angle and with needle bevel facing upwards
- C: Wiping rubber stopper of vial with sterile alcohol pad in a back and forth direction
- D: Never blocking airflow between the HEPA filter and the sterile product being prepared
- E: Only touching flat end at the top of the plunger of a syringe

Answer: C

Sterile Product Preparation: Equipment, Technique & Monitoring

QUESTIONS?



Sterile Product Preparation: Equipment, Technique & Monitoring

Thank you for
your Attention
and Participation!



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